

## **ARGUMENTS**

### **I. Rejection of claims 1-5, 14-17, and 21-22 under 35 U.S.C. §103**

The Examiner rejected claims 1-5, 14-17, and 21-22 under 35 U.S.C. § 103(a) as being obvious over Kyle in view of Crozier and Schweikhardt. The Examiner asserts that Kyle teaches an infant formula comprising DHA and ARA and that the presence of those two fatty acids in infant food is critical for the “healthy growth” of the infants. Although Kyle does not teach the administration of that infant formula to preterm infants, the Examiner asserts that Crozier teaches that “the presence of ARA and DHA in food is particularly important for the proper growth and development of preterm infants because they are unable to synthesize sufficient ARA and DHA.” The Examiner admits that while both Kyle and Crozier fail to teach or suggest the amounts of ARA and DHA now claimed by the present claims, Schweikhardt discloses such amounts. Thus, the Examiner concludes that it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer the infant formula of Kyle to the preterm infants of Crozier in the amounts suggested by Schweikhardt.

The product claims, 14 – 17 and 22, have been cancelled without prejudice to re-file in a continuing application. Therefore, the only claims currently at issue are the method claims.

Even if one of ordinary skill in the art were to combine Kyle, Crozier and Schweikhardt, a combination that Applicants contend is not suggested by the references, the combination would still not teach or suggest every one of the limitations in the claims of the present application. See MPEP § 2142 - § 2143 (explaining that the

prior art references, when combined, must teach or suggest all the claim limitations); *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (“All words in a claim must be considered in judging the patentability of that claim against the prior art.”). Specifically, the combination of Kyle, Crozier and Schweikhardt does not teach or suggest a method for enhancing the weight gain of preterm infants by administering to the preterm infants a weight gain enhancing amount of DHA and ARA as required by the amended claims of the application.

The Examiner asserts that the claims are directed to a formula and its ultimate utility, i.e., feeding a preterm infant an formula comprising ARA and DHA. As the claims have been amended, Applicant respectfully submits that this is not the case. The claims are directed to a “method for enhancing the weight gain of preterm infants” and not to the infant formula itself. The utility of the method involves enhancing the weight gain of preterm infants. Such a utility has not been suggested by the cited references and their combination cannot be made without this suggestion.

The Examiner asserts that the enhancement of weight gain in preterm infants through the provision of DHA and ARA is an advantage that flows naturally from the suggestion of the prior art. Again, this assertion is incorrect. The references, even when combined, actually teach away from the present invention.

Kyle does not teach the administration of DHA and ARA to preterm infants at all. In fact, the only relevant reference in the entire patent states that “it is critical that the infant receive adequate amounts of PUFAs to insure proper structural and organ development.” Kyle, col. 1, lines 32-34. This portion of the patent does not even specify that the PUFA should be DHA or ARA. It certainly does not teach or suggest

that these supplements would enhance weight gain in preterms. Therefore, Kyle provides no support for the obviousness analysis.

While Crozier relates to preterm infants, it fails to teach or suggest that enhancing the weight gain of preterm infants would be beneficial. In addition, Crozier fails to suggest that it is even possible to enhance the weight gain of preterm infants by the administration of DHA and ARA. Crozier does however, cite a study by Carlson, in which preterm infants given supplemental DHA actually demonstrated a decrease in weight gain. Carlson, *et al.*, *Effect of Long-Chain n-3 Fatty Acid Supplementation on Visual Acuity and Growth of Preterm Infants with and without Bronchopulmonary Dysplasia*, Am. J. Clin. Nutr. 63:687-97 (1996). In Carlson, absolute growth measurements showed that DHA-supplemented preterm infants weighed significantly less than standard formula-fed preterms at 2, 9 and 12 months. Carlson, Am. J. Clin. Nutr. 63 at 692. The absolute growth measurements are shown in Table 6, on page 694. Carlson also notes that “[i]n the only other trial designed to study the effects of n-3 LCFA supplementation on growth, supplemented infants grew less well than infants fed commercially available formulas.” *Id.* (citing Carlson, *et al.*, *First Year Growth of Preterm Infants Fed Standard Compared to Marine Oil n-3 Supplemented Formula*, Lipids 27:901-07 (1992)). Based on its reliance on Carlson and its lack of teaching otherwise, Crozier simply does not suggest enhancing the weight gain of preterm infants by administering to them a formula containing a weight gain enhancing amount of DHA and ARA. In fact, the citation of the Carlson study teaches away from the improved weight gain of the present invention.

Schweikhardt does not teach that its fat mixture has any particular effect at all on infants. Schweikhardt states that the “fat mixture according to the invention is suitable for the preparation of an infant and premature baby feed.” Schweikhardt translation, pg. 5. It does not suggest that a premature infant can have an enhanced weight gain due to DHA and ARA supplementation.

Therefore, the combined teachings of Kyle, Crozier and Schweikhardt, taken as a whole (*i.e.*, that DHA causes a decrease in growth in preterm infants), would lead one of ordinary skill in the art away from enhancing the weight gain of preterm infants. As a result, the claimed method is patentably distinct over the combination of Kyle, Crozier and Schweikhardt.

Regarding the establishment of unexpected results, the Examiner points out that it is Applicant’s burden to explain any proffered data and establish how the results are unexpected and significant. The Examiner also points out that the claims must be commensurate in scope with any evidence of unexpected results. Lastly, the Examiner asserts that the Applicant must compare the claimed subject matter with the closest prior art in order to be effective to rebut a case of obviousness.

Applicant submits that it has previously met its burden to explain the data and establish how the results are unexpected and significant. Applicant’s unexpected results are illustrated by the data presented in the specification. Table 3 (page 28) shows the mean weight gains for preterm infants, with weight gains of 30.7 grams/day (g/d) for the Control group and 34.7 g/d for the DHA+ARA group. Table 5 also clearly demonstrates a significant difference in weight gain between the control and DHA+ARA fed groups. This is also illustrated in Figure 1, which is a graphical representation of the

weight gain results between the DHA+ARA and Control groups. Further, at page 23, lines 7-13 of the Application, Applicants report the results as follows:

Post-hoc analysis reveals that infants on DA [DHA & ARA-enhanced formula] grew faster than infants receiving C [regular formula] and D [DHA-enhanced formula] (See table 5 and figure 1). This enhanced growth provided faster “premature infant catch-up” compared to C and D. Weight achieved by the DA group (3198 g) was higher than C (3075 g) and D (3051 g) at 40 weeks post-conceptual age but had not fully caught up to the term weight (3438 g) of group H [breast-fed term infants] (See table 4 and figure 2). This catch up trend continued through 48 to 57 weeks by which time the mean weight of group DA did not differ from group H while groups C and D remained significantly lower. (Emphasis added).

When compared to Crozier as the closest prior art, the results of the present invention are completely unexpected. Crozier fails to teach or suggest that enhancing the weight gain of preterm infants would be beneficial or that it is even possible to enhance the weight gain of preterm infants by the administration of DHA and ARA.

Based on the results of Carlson, upon which Crozier relies, it is clear that any increase in weight gain due to DHA and ARA supplementation would be surprising and unexpected. Crozier does not suggest the benefit of the claimed invention, as asserted by the Examiner. Crozier nor any other reference discloses any range of enhanced weight gain due to DHA and ARA supplementation. Thus, the present invention is an unexpected result in kind, not merely in degree. Applicant’s specification contains specific data indicating substantially improved results over the prior art and points out that the results were unexpected and surprising. This should suffice to establish unexpected results. *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995).

Applicant additionally asserts that the amended claims of the present invention are commensurate in scope with the evidence of unexpected results. The amended

claims disclose a method for enhancing the weight gain of preterm infants by administering to them a weight gain enhancing amount of DHA and ARA. The experimental data in the application demonstrates an enhanced weight gain as a result of the administration of DHA and ARA. Thus, the scope of the amended claims are commensurate in scope with the evidence of unexpected results.

In summary, in view of the foregoing arguments and amendments, Applicants respectfully submit that claims 1-5 and 21-22 are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. Applicants believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application. The Examiner is invited to telephone the undersigned should any issues remain after the consideration of this response.

Please charge any additional fees that may be required to Deposit Account No. 50-2548.

Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH

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Date



Nichole T. Andrighetti  
Registration No. 56,508  
Meridian, Suite 1700  
1320 Main St.  
Columbia, SC 29201  
Phone: (864) 250-2292  
Fax: (864) 250-2394